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510(k) SUMMARY

Intrinsic Therapeutics Fixation Staple AUG - 3 2007

Applicant:

Intrinsic Therapeutics, Inc.
30 Commerce Way
Woburn, MA 01801
USA

Phone: (781) 932-0222
Facsimile: (781) 932-0252

Contact Person: Krishna Uppugonduri
Date Prepared: June 14, 2007

Trade Name of Device

Intrinsic Therapeutics Fixation Staple

Common or Usual Name

Fixation Staple

Classification Name

Staple, Fixation, Bone
21 CFR 888.3030, Product Code: JDR

Predicate Devices

(1) Conmed Linvatec Fixation Staple
(2) Smith & Nephew Fixation Staple

Intended Use / Indications for Use

The Intrinsic Therapeutics Fixation Staple is intended for providing soft tissue fixation to bone in orthopedic procedures such as:

1. Tendon repairs, transfers, or transplants, such as in the treatment of paralytic conditions, tendon avulsions or ruptures, in which the tendon is fixed to the bone.
2. Ligament repairs, reconstruction, or replacement in which the ligament is fixed to the bone.

Device Description/Technological Characteristics

The Intrinsic Therapeutics Fixation Staple is made from 6Al 4V ELI Titanium conforming to ASTM F136. The legs of the staple have barbs and are curved to provide strength in bone fixation. The staple is provided sterile. A reusable insertion tool is provided to facilitate insertion of the staple.

Performance Data

Benchtop testing was performed on the Intrinsic Therapeutics Fixation staple and the predicate devices. The Intrinsic Therapeutics Fixation Staple functioned as intended and met the test criteria. Package integrity tests were performed to support the listed shelf life.

Substantial Equivalence

The Intrinsic Therapeutics Fixation Staple is as safe and effective as the predicate devices. The Intrinsic Therapeutics Fixation Staple has the same intended use, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Intrinsic Therapeutics Fixation Staple and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Intrinsic Therapeutics Fixation Staple is as safe and effective as the predicates. Thus, the Intrinsic Therapeutics Fixation Staple is substantially equivalent.

Conclusions:

Based upon the proposed device's design and technological characteristics, indications for use, and results of comparative testing against predicate devices, the Intrinsic Therapeutics Fixation Staple is considered to be substantially equivalent to the cited legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Intrinsic Therapeutics, Inc.
% Mr. Krishna Uppugonduri
30 Commerce Way
Woburn, MA 01801

AUG - 3 2007

Re: K071637
Trade/Device Name: Intrinsic Therapeutics Fixation Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: II
Product Code: JDR
Dated: June 14, 2007
Received: June 15, 2007

Dear Mr. Uppugonduri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

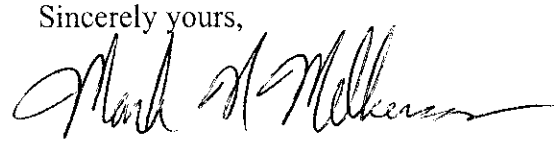
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K071637

Device Name: Intrinsic Therapeutics Fixation Staple

Indications for Use:

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2. Ligament repairs, reconstruction, or replacement in which the ligament is fixed to the bone.

Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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